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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/260,536	06/16/1994	ROBERT M. LORENCE	57704	4057

7590 04/16/2004

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/260,536	LORENCE ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 3.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 332-355 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 332-355 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/10/03, 1/8/04(2), 7/28/03, and 6/30/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Examiner Emily Le.

Acknowledgment of Amendment(s)

2. Applicant's Responsive Amendment, filed January 08, 2004 is acknowledged by the office.

Status of Claims

3. Claims 1-331 are canceled. Claims 332-355 are currently pending and under examination.

Specification

4. The disclosure is objected to because of the following informalities: The Field of the Invention and Summary of the Invention is not descriptive of the instantly claimed invention.

5. The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 350-352 recites the limitation "the amount" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claim.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 332-355 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1)the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The nature of the claimed invention is directed to a method of treating cancer in a mammal having a tumor with the administration of the Newcastle Disease Virus (NDV).

The scope/breadth of the claims encompasses all mammals, including humans and non-human animals and all types of cancer.

The specification, including the working examples provided, teaches that at different concentrations of NDV, tumor regression is observed in mice that have been xenografted with human tumor cells. However, the specification does not teach how such finding would correlate to the use of NDV in mammals, including humans and non-human animals having a tumor. Therefore, the specification, including the working examples, is not enabling for one skilled in the art to practice the claimed invention.

Like the specification, the prior art teach that tumor regression is observed in mice with xenografted tumors that has been treated NDV. However, the prior art also teach that there is an inconsistency and lack of reproducibility of xenografted tumor growth in mice. (See Sharkey et al. in "Experience in Surgical Pathology with Human Tumor Growth in the Nude Mouse". The Nude Mouse in Experimental and Clinical Research, 1978, chapter 10, pages 187-214.)

Although, the state of the art teach that NDV-based anticancer therapy has been reported to be of benefit in different clinical studies. However, the overall level of evidence that is provided does not support the virus's role in cancer as an anticancer agent. The use of NDV as an anticancer agent is not conclusive, as noted by the National Cancer Institute's complementary and alternative medicine (CAM) on NDV. Therefore, due to the lack of evidence that would provide a nexus between NDV and the regression of tumors in mammals having a tumor, the

quantity of experimentation required of one skilled in the art to practice the claimed invention would be tremendous for the following reasons:

Neither the specification, the prior art, nor the state of the art teach i) how the existing or induced cellular and humoral immune responses impact on the efficacy of virus in treating cancer; ii) how the toxicity of the virus affect non-cancerous tissue; iii) the efficacy of the virus in mammals, humans and non-humans, having a tumor; iv) how different tumors affect the efficacy of the treatment because inherent infectability and capacity to support viral replication varies between and within specific tumors and individual patients; v) how the timing, quality and magnitude of the immune system's response affect the efficacy of the viral therapy; vi) if the virus can effectively avoid recognition my the host's immune system; and vii) the effective dosage amount to cause tumor regression.

With the exception of item vii), all of the listed items are discussed by Kirn et al. as factors that must be considered in selecting a virus for use in anticancer therapy and the factors that influence efficacy of such therapy. (See Kirn et al. "Replicating viruses as selective cancer therapeutics". Molecular Medicine Today, 1996, 519-527.)

Thus, in view of the discussion above and evaluation of the wands factors, the instant specification is not enabling one skilled in the art to practice the claimed invention without an undue burden.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed

invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 332, 337-339, 343, 348, 350 and 355 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 13 and 16-18 of copending Application No. 10/700143. Although the conflicting claims are not identical, they are not patentably distinct from each other

because both claimed invention are directed to method of treating cancer with Newcastle Disease Virus.

12. Claims 332-334, 336-340, 343-345, 347-350, 353 and 355 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 157-158, 161-166, 173-174, 183-185 and 196-197 of copending Application No.09/958809. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed invention are directed to method of treating cancer with Newcastle Disease Virus.

13. Claims 332-334, 336-340, 343-345, 347-349, 353 and 355 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6-9, 11, 19, 50-52, 63, 116-117, 136 and 138 of copending Application No.10/167652, US PGPUB No. 2003/0165465. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed invention are directed to method of treating cancer with Newcastle Disease Virus.

14. Claims 332-334, 336-340, 343-345, 347-349, 353 and 355 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6-9, 11, 19, 50-52, 63, and 116-117 of copending Application No.10/044,955, US PGPUB No. 20030044384. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed invention are directed to method of treating cancer with Newcastle Disease Virus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le

Emily Le

Shanon Foley
Patent Examiner, AU 1648